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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/836,804 04/17/01 MESFIN

G 6267.N

HM12/1024

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EXAMINER

JIANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/836,804

Applicant(s)

MESFIN ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

This application claims priority to provisional application Serial No. 60/198,688.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression " formula (I) or formula (II) " in claim 13 renders claim 13 indefinite. The expression " formula (I) or formula (II) " in claim 13 is not defined by the claim. Therefore, the scope of claims is indefinite as to the composition encompassed thereby.

Claim 13 provides for the use of a compound of formula I or II in claim 1 or 7, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

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35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

In order to expedite prosecution, the claim will be examined on the merits as a method of manufacture herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hester et al. (WO 9854161, PTO-892) in view of Nair et al. (U, PTO-892)

Hester et al. discloses that the instant active compounds as being antibacterial agents are useful in pharmaceutical compositions and methods for treating or combating bacterial infections in animals. Hester et al. also discloses that the instant active compounds are administered in the instant range orally and/or parentally. Hester et al. further discloses methods of manufacture of the instant compounds. See abstract, page 32 line 27 to page 33 line 13, page 42-81, page 109 lines 24-27 and claim 3 therein.

Hester et al. do not expressly disclose the employment of the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

Nair et al. teach that bacteria are important cause of bone diseases and induce bone destruction, and many bacteria are capable of stimulating bone matrix loss. See title and abstract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal because active compounds herein are known antibacterial agents and known to be useful broadly in methods for treating or combating bacterial infections in animals according to Hester et al. Bacteria are known to be important cause of bone diseases, to induce bone destruction, and to stimulate bone matrix loss according to Nair et al. Therefore, one of ordinary skill in the art would have reasonably expected that the instant compounds known as antibacterial agents would have beneficially therapeutical effect on the treatment or prevention of osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (WO 9912914, PTO-892) in view of Nair et al. (U, PTO-892)

Yoshida et al. discloses that active compounds therein within the instant claim as antibacterial agents exhibit excellent antibacterial activity. Yoshida et al. further discloses methods of manufacture of the instant compounds. See abstract.

Yoshida et al. do not expressly disclose the employment of the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal. Yoshida et al. do not also disclose that the instant active compounds are administered in the instant range orally and/or parentally.

Nair et al. teach that bacteria are important cause of bone diseases and induce bone destruction, and many bacteria are capable of stimulating bone matrix loss. See title and abstract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal, and to administer the active compounds herein in the instant range orally and/or parentally.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal because active compounds herein are known antibacterial agents and known to exhibit excellent antibacterial activity in animals according to Yoshida et al. Bacteria

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are known to be important cause of bone diseases, to induce bone destruction, and to stimulate bone matrix loss according to Nair et al. Therefore, one of ordinary skill in the art would have reasonably expected that the instant compounds known as antibacterial agents would have beneficially therapeutical effect on the treatment or prevention of osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

Additionally, one of ordinary skill in the art would have been motivated to administer the active compounds herein in the instant range orally and/or parentally since the optimization of amounts of active agents to be administered and determination of routes of administration from those well known in the art is considered well within the skill of artisan, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

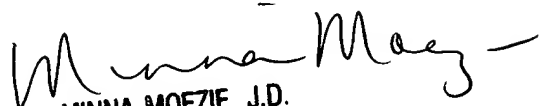
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
October 15, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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